

CLAIMS

1. An effervescent formulation comprising apomorphine.
- 5 2. An effervescent formulation according to Claim 1 comprising multilayer effervescent microspheres.
3. An effervescent formulation according to Claim 2 wherein the multilayer effervescent microspheres contain an acidic substance, a basic
10 substance and water-soluble isolating agent.
4. An effervescent formulation according to Claim 3 wherein dissolution in water of the multilayer effervescent microspheres leads, after almost immediate effervescence, to a solution or a homogeneous dispersion
15 of the apomorphine.
5. An effervescent formulation according to Claim 4 wherein the water-soluble isolating agent is dispersed in the entire bulk of each microsphere, the latter having a two-layer structure: a layer of acidic
20 substance in which is dispersed the water-soluble isolating agent and a layer of alkaline substance in which is dispersed the water-soluble isolating agent.
6. An effervescent formulation according to Claim 4 wherein the
25 water-soluble isolating agent is in the form of a thin film separating the acidic and alkaline substances such that each microsphere has a three-layer structure: a layer of acidic substance and a layer of alkaline substance separated by a layer of water-soluble isolating agent.

7. An effervescent formulation according to any of the preceding claims wherein the apomorphine is present in a unit dose amount of from 0.5mg to 50mg.
- 5 8. An effervescent formulation according to Claim 7 wherein the apomorphine is present in a unit dose amount of 2mg to 3mg.
9. An effervescent formulation according to any of the preceding claims wherein the formulation is presented in a tablet form.
- 10 10. An effervescent formulation according to Claims 1 to 8 wherein the formulation is presented in a powder form.
11. An effervescent formulation according to any one of the preceding
15 claims wherein the apomorphine is present within a microsphere.
12. An effervescent formulation according to any one of the preceding Claims 1 to 11 wherein the apomorphine is not present within a microsphere.
- 20 13. An effervescent formulation according to any of the preceding claims obtained or obtainable by the process of any one of Claims 16 to 25.
14. An effervescent formulation according to any one of the previous
25 claims for use in medicine.
15. A pharmaceutical composition comprising an effervescent formulation according to any one of Claims 1 to 13 and a pharmaceutically acceptable carrier.

16. A process for making an effervescent formulation containing apomorphine.
17. A process according to Claim 16 wherein the effervescent
5 formulation comprises multilayer effervescent microspheres containing an acidic substance, a basic substance, and a water-soluble isolating agent which upon dissolution in water leads, after almost immediate effervescence, to a solution or a homogeneous dispersion of apomorphine.
- 10 18. A process according to Claim 17 wherein the acidic and/or basic substances contains or contain apomorphine.
19. A process according to Claim 16 or Claim 17 wherein the apomorphine is not present in microspheres.
- 15 20. A process according to Claim 18 which employs the method of rotary granulation in a fluidized air bed.
21. A process according to Claims 17 to 20 wherein basic substance also
20 contains an edible diluant and/or flavourings and/or sweeteners.
22. A process according to Claims 17 to 21 wherein the apomorphine is present in an amount to give from 0.5mg to 50mg in the final unit dosage form.
- 25 23. A process according to Claim 22 wherein the apomorphine is present in an amount to give from 2mg to 3mg in the final unit dosage form.
24. A process according to any one of Claims 16 to 23 further
30 comprising preparing the microspheres into a tablet.

25. A process according to Claim 24 wherein the apomorphine is present on or between the microspheres in the tablet.

5 26. An effervescent formulation of apomorphine obtained or obtainable by the process of any one of Claims 16 to 25.

27. A method of treating human male or female sexual dysfunction comprising administering to said human an effervescent formulation of
10 apomorphine according to any one of Claims 1 to 13 and/or obtained or obtainable by a process as defined in any one of Claims 16 to 26 and/or a pharmaceutical composition according to Claim 15.

28. Use of an effervescent formulation of apomorphine according to any
15 one of Claims 1 to 13 and/or obtained or obtainable by a process as defined in any one of Claims 16 to 26 and/or a pharmaceutical composition according to Claim 15 in the manufacture of a medicament for the treatment of male or female sexual dysfunction.

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